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ZOLL Medical Corporation

Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105
U.S.A.

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978 421-0025 Main Fax

ZOLL

JUN 2 4 2005

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Sean Reynolds

(978) 421-9655, Ext. 9386

Date Summary Prepared:

May 16, 2005

Device:

ZOLL M Series 12SL™ Analysis Option

Classification:

Electrocardiograph: Class II (21 CFR 870.2340)

Automactic External Defibrillators: Class III (21 CFR 870.5310)

Description:

The ZOLL M Series products (K972241) combine a defibrillator, ECG Monitor, Noninvasive Transcutaneous Pacing, Pulse Oximetry (K982992), End Tidal CO_2 (K993036), 12-Lead ECG Monitoring (K991556), Non-Invasive Blood Pressure measurement (K002029) Invasive Blood Pressure and Temperature (K011865) and data printing and recording in a single instrument.

The 12SL™ Analysis Option using the GE/Marquette 12SL™ Algorithm is useful in the diagnosis of patients with acute myocardial infarction (AMI) and is useful in the interpretation and documentation of other transient cardiac arrhythmias that may occur. The 12-Lead ECG Analysis is indicated for the recording and analysis of 12 Lead ECG signals acquired from adult and pediatric patients in the supine, resting position. The Acute Cardiac Ischemia–Time Insensitive Predictive Instrument (ACI-TIPI) and Thrombolytic Predictive Instrument (TPI) are decision aids for qualified clinicians who may currently wish to calculate ACI–TIPI and TPI in adult patients.

K051475
p 2/2

Intended Use:

The ZOLL M Series with 12SL™ is intended for the recording and automated analysis of 12-Lead ECG signals acquired from adult and pediatric patients in the supine, resting position.

Substantial Equivalence:

The features and functions of the proposed enhancement to the M Series 12SL™ Analysis Option are substantially equivalent to the current features and functions of the M Series 12SL™ Analysis Option (K991556), cleared for use on 2/28/2000.

Comparison of Technological Characteristics

The ZOLL M Series 12SL™ Analysis Option utilizes the same interpretive features and functions to those of the currently marketed ZOLL M Series 12SL™ Analysis Option (K991556). The device acquires an ECG signal through a 10-wire cable assembly and commonly used patient electrodes placed in a standard 12-Lead configuration. The device is also capable of storing that data to memory and/or transmitting that data via cellular telephone, RS232 port, or wirelessly using Bluetooth™ technology.

Performance Testing:

Extensive performance testing ensures that the ZOLL M Series 12SL™ Analysis Option performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL M Series 12SL™ Analysis Option demonstrates that its features and functions are substantially equivalent to those of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2005

Zoll Medical Corporation
Worldwide Headquarters
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
269 Mill Road
Chelmsford, MA 01824-4105

Re: K051475
Trade Name: Zoll M Series 12SL™ Analysis Option
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: MKJ
Dated: May 26, 2005
Received: June 3, 2005

Dear Mr. Reynolds:

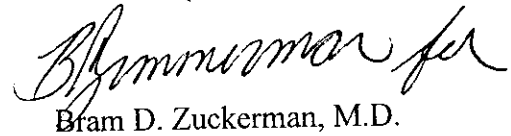
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051475

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **ZOLL M Series 12SL™ Analysis Option**

Indications for Use:

The 12-Lead ECG Analysis is useful in the diagnosis and treatment of patient with acute myocardial infarction (AMI). 12-Lead ECG Analysis is also useful in the interpretation and documentation of other transient cardiac arrhythmias that may occur. When used in the prehospital setting, the 12-Lead analysis results can be of assistance in diagnosis and treatment decisions once the patient has arrived in the hospital emergency department.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051475